TIP FOR MEDICAL IMPLANT DELIVERY SYSTEM

CROSS-REFERENCE TO RELATED APPLICATIONS

The present application claims the benefit of the filing date of U.S. Provisional Application No. 61/374,435, filed Aug. 17, 2010, the disclosure of which is hereby incorporated by reference herein.

BACKGROUND OF THE INVENTION

The present disclosure relates to medical implant delivery systems and methods and, more particularly, to delivery systems and methods for positioning an expandable prosthetic heart valve in a patient's vasculature.

Prosthetic heart valves are usually implanted in the human heart to replace natural valves. These valves essentially function as check valves, permitting the blood to flow through the valves in a downstream direction, but blocking blood flow in a reverse or upstream direction. Some prosthetic heart valves include an annular valve housing or body with a central orifice and occludes. The orifice provides a passageway for the blood, and the occludes open and close to regulate the passage of blood. For instance, U.S. Pat. Nos. 5,876,436 and 6,719,790 describe in detail specific prosthetic heart valves. Both of these references are hereby incorporated herein by reference in their entireties.

One type of prosthetic heart valve is collapsible to a relatively small circumferential size. This type of prosthetic heart valve can be delivered into a patient less invasively than valves that are not collapsible. For example, a collapsible valve may be delivered into the patient via a tube-like delivery apparatus such as a catheter, a tracer, a laparoscopic instrument, or the like. This can avoid the need for a more invasive procedure such as full open-chest, open-heart surgery. When the collapsed valve has reached the desired implant site in the patient (e.g., at or near the annulus of the patient's heart valve that is to be effectively replaced by the prosthetic valve), the prosthetic valve can be expanded to full operating size and released from the delivery apparatus. Typically, in its full operating size, the prosthetic valve engages adjacent native tissue of the patient to firmly anchor itself in the patient.

Because valves of the type described above are basically implanted by remote control (because the valve is inside the patient at the far end of delivery apparatus that is manipulated and controlled from its proximal end outside the patient), it can be difficult to get the valve to exactly the right location in the patient before releasing it from the delivery apparatus. Improvements are therefore sought with respect to how such valves are deployed.

One percutaneous delivery method entails introducing a collapsible prosthetic heart valve through a patient's femoral artery. This delivery method is referred to as a transfemoral approach. In transfemoral valve implantation, the collapsible prosthetic heart valve is delivered in a retrograde manner from the femoral artery through the aortic arch to, for example, the native aortic valve annulus.

A delivery system and an introducer may be used to deliver the prosthetic heart valve to the native aortic valve annulus using the transfemoral approach. As seen in FIGS. **1** and **2**, a conventional delivery system may include a distal sheath **30** for slidably enclosing a valve-containing compartment, and a proximal outer shaft **20** for controlling sliding movement of the distal sheath to open and close the compartment. The delivery system may further include a tip **32** having a maximum diameter that is substantially similar to the outer diameters of the distal sheath **30** and the proximal outer shaft **20**. For example, in an 18F delivery system, the proximal outer shaft **20**, the distal sheath **30**, and the maximum diameter of the tip **32** are each about 18F. In such conventional delivery systems, the distal end **34** of the distal sheath **30** may be outwardly flared as a consequence of contacting the proximal surface of the tip **32**. The flared distal end **34** of the distal sheath **30** may catch on body tissue as the delivery system is advanced in the patient's vasculature. For instance, the distal end **34** of the distal sheath **30** may catch on the aortic valve, the calcified aortic annulus, and/or lesions or calcified tissue in the aortic arch.

During transfemoral valve implantation, the distal sheath **30** of the delivery system is bent significantly to pass through the aortic arch A, which significantly biases the sheath toward the outside wall W of the aortic arch A, as illustrated in FIG. **3**. Consequently, the flared distal end **34** of the distal sheath **30** may forcibly contact at least a portion of the outside wall W as the delivery system is advanced toward the native aortic valve annulus. The distal end **34** of the distal sheath **30** may also catch on calcified tissue C located on the outside wall W of the aortic arch A, as seen in FIG. **3**. The contact between the distal sheath **30** and the outside wall W of the aortic arch A may cause various adverse effects on the patient. For instance, when the delivery system passes through the aortic arch A, the distal end **34** of the distal sheath **30** may damage the outside wall W of the aortic arch A, or may sever calcified tissue C, which may in turn cause an embolism. It is therefore desirable to minimize the contact between the distal sheath **30** and body tissue when advancing a delivery system using the transfemoral delivery approach.

BRIEF SUMMARY OF THE INVENTION

The present disclosure relates to a delivery system for delivering and deploying a medical implant, such as a prosthetic heart valve. The delivery system includes an elongated support member configured to hold a medical implant; a sheath having an outer diameter surrounding at least a portion of the elongated support member, the sheath being movable between a proximal position and a distal position relative to the elongated support member; and a tip attached to the elongated support member and positioned at a distal end of the sheath when the sheath is in the distal position, the tip having a compressed condition, an expanded condition, and a variable diameter along a length thereof. In the expanded condition, the maximum diameter of the tip is larger than the outer diameter of the sheath. The maximum diameter of the tip in the expanded condition may be about 0.005 inches to about 0.020 inches larger than the outer diameter of the sheath.

The tip may be made at least partly of a compressible material selected from the group consisting of polyether block amide, polyurethane, and silicone rubber. At least a first portion of the tip may have a first stiffness of a second portion of the tip.

In certain embodiments, the tip may have a closed inner cavity containing a fluid substance. The fluid substance may be selected from the group consisting of a liquid, a gel and a gas.

The tip may include an outer member formed from a porous material and an inner member formed from an elastic material. The outer member may surround at least a portion of the inner member. A plurality of longitudinal recesses may be formed along the length of the tip.

The tip may be formed by an injection molding process, including a multi-step injection molding process. The injec-